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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/521,086 | 03/07/2000 | Miladin P. Lazarov | 11699-002001 | 9173 |

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EXAMINER

PAULRAJ, CHRISTOPHER

ART UNIT

PAPER NUMBER

1773

DATE MAILED: 04/22/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

MF/1

| | | |
|------------------------------|------------------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/521,086 | LAZAROV ET AL. |
| | Examiner | Art Unit |
| | Christopher G. Paulraj | 1773 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 25 January 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-3,5-17 and 19 is/are pending in the application.

4a) Of the above claim(s) 12-16 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-3,5-11,17 and 19 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-3,5-17 and 19 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

1. The amendment filed on January 25, 2002 has been entered. Claims 1-3, 5-17, and 19 are pending.
2. Claims 12-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.
3. Applicant's arguments with respect to claims 1-3, 5-11, 17, and 19 have been considered but are moot in view of the new ground(s) of rejection. As explained in further detail below, the process limitation added in the amendment does not distinguish the claimed product from the applied reference.

Claim Rejections - 35 USC § 112

4. Claims 5, 6, 10, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 5 appears to contain a typographical error. Instead of a thickness between 0 and 5 μm , it recited 9 and 5 μm . Claim 6, reciting a specific resistance between 10 and 10 $\mu\Omega\text{.cm}$, also appears to be in error.
6. Claim 10 recites an alternative limitation using improper Markush group terminology. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a

Markush group, is recited as "wherein R is a material selected from the group consisting of A, B, C and D." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). It is improper to use the term "comprising" instead of "consisting of." Ex parte Dotter, 12 USPQ 382 (Bd. App. 1931). Another acceptable form is recited as "wherein R is A, B, C or D." See MPEP 2173.05(h).

7. Claim 19 is still in improper dependent form. A dependent claim cannot incorporate different features from two different sets of claims. See MPEP 608.01(n).

Claim Rejections - 35 USC § 102

8. Claims 1, 3, 5, 6, 7, 8, 11, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Davidson (U.S. Patent 5,496,359).

Davidson discloses zirconium oxide and zirconium nitride coated biocompatible leads, in which the coating is applied by physical or chemical vapor deposition (abstract). The coated surfaces may be further coated with other compositions such as heparin and protein to further enhance biocompatibility (col. 4, lines 20-25). The coatings can have a thickness of 3 to 6 microns (col. 8, lines 26). The claimed specific resistance (claim 6) is considered to be met because the same materials are used. The article may be used as stents (col. 3, line 21).

The amended claims add a process limitation. It is the examiner's position that the article disclosed by Davidson is identical to or only slightly different than the claimed article prepared by the method of the claim(s), because both contain

the same materials. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or an obvious variation from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983). The Davidson reference either anticipated or strongly suggested the claimed subject matter. It is noted that if the applicant intends to rely on Examples in the specification or in a submitted Declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with the Davidson reference.

Applicants argue that Davidson implies that dense coatings are critical and that applicants recited pressure of 10^{-4} to 10^{-2} mbar would result in porous coatings. However, the terms dense and porous are relative terms. What may be considered to be "dense" by Davidson, may nevertheless be porous enough to meet the instant claim limitations. Applicants need to submit evidence in declaration form showing that the pressures recited in the instant claims would result in a patentably distinct product than that of Davidson.

Furthermore, Applicants have not sufficiently shown that the “standard physical or chemical vapor deposition methods” disclosed by Davidson (col. 11, lines 15-20) would use lower pressures than the claimed range. Applicants have submitted pages from the instruction manual for the Temescal Electronic Beam Source, which shows that the vacuum chamber is evacuated to 1×10^{-4} , (0.1 micron or less). This converts to pressure of 1.33×10^{-4} mbar, which falls within the claimed range. Applicants have not submitted any evidence in support of their argument that pressure while metalization is taking place would be lower than the starting pressure. Applicants have also not submitted any evidence showing that the pressure disclosed in the instruction manual is considered “standard” in the art.

Claim Rejections - 35 USC § 103

9. Claims 1-3, 5-8, 10-11, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarov et al. (WO96/25960) in view of Davidson. U.S. Patent 6,110,204 is used to serve as an English translation of the WO document.

Lazarov et al. discloses implants for use in the human body, where a substrate is coated with a material which contains chemical compounds between one or more metals (M) of group IV A of the periodic system (Ti, Zr, and Hf), with 2 to 45 % of the volume of the coating being formed by voids. The formula of Mn_xO_y recited in the abstract meets the requirements of claim 3. The coating has a preferable surface resistance of 30 to 30000 $\mu\Omega.cm$ (col. 3, lines 25). The underlying substrate can be gold or tantalum (claims 7,14). The deposition is

done at gas pressures that can range from 10^{-2} to 10^{-4} hPa (col. 7, lines 15-40).

The implant can be used as stents (col. 1, line 10).

Lazarov et al. does not specifically teach that a protein, peptide, and/or saccharide containing substance can be applied onto the group IV A metal layer. However, in light of what Davidson teaches, one skilled in the art would have found it obvious to apply such a substance such as heparin onto the metal layer. The motivation for doing so would have been to improve the biocompatibility of the article.

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarov et al. in view of Davidson as applied to claim 1 above, and further in view of Guire (U.S. Patent 5,263,992).

Davidson does not specifically teach the use of albumin as one of the substances that may be coated to improve biocompatibility. However, Guire discloses that solid surfaces have been coated with biochemical materials such as heparin, albumin, and streptokinase to enhance thromboresistance (col. 1, lines 66-68). One skilled in the art, motivated to improve thromboresistance, would have found it obvious to apply albumin onto the metal layer disclosed by Lazarov et al.

Information Disclosure Statement

10. Receipt of Information Disclosure Statement filed on January 25, 2002 is acknowledged and has been made of record. Foreign language documents were only considered to the extent of what their English abstracts provided.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher G. Paulraj whose telephone number is (703) 308-1036. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Blaine Copenheaver can be reached on (703) 308-1261. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0661.

cgp
April 18, 2002

Paul Thibodeau
Paul Thibodeau
Supervisory Patent Examiner
Technology Center 1700